REMARKS

In order to more particularly point out and distinctly claim the subject matter that applicants regard as their invention, new claims 16 to 25 have been derived from claims 1, and claims 3 to 7. New claims 26 to 32 have been derived from claims 8, and claims 10 to 14.

Duclos et al. (US 5,776,495)

The product disclosed by Duclos et al. is different from the product disclosed in the current invention. Duclos et al. (US 5,776,495) discloses a process "for the production of a solid dispersion of at least one therapeutic agent in a hydrophilic carrier having enhanced solubility in an aqueous media" which "comprises dissolving at least one therapeutic agent in a volatile organic solvent containing a very hydrophilic polymer and evaporating the solvent to dryness to form a co-precipitate of therapeutic agent and hydrophilic polymer" (see column 2, lines 17-24). Further, Duclos et al. discloses that "the solid dispersions are systems in which one or several active ingredients are dispersed in the solid state (microparticular, even molecular) in an inert solid vehicle" (see column 2, line 55-57).

Unlike the disclosure of Duclos et al., the current application discloses a pharmaceutical composition consisting of submicron to micron size solid fenofibrate [i.e., a therapeutic agent] microparticles and water in which a combination of phospholipid and one or more nonionic, anionic or cationic surface modifier(s) is coated or adhered onto the surfaces of the solid fenofibrate microparticles. Furthermore, the surface modifier(s) have their hydrophilic portion sticking into the aqueous solution and their lipophilic

portion adsorbed at the surfaces of the microparticles. The microparticles can be in the form of a suspension (in water), or in the form of a powder dried (but not made 100% anhydrous as the particles of Duclos et al.) by lyophilization, fluid or spray drying, methods which as the Examiner knows, provide powders containing residual levels of water. The composition of the microparticles and the method of preparing them as solid fenofibrate, phospholipid, surface modifier(s) and water are different from the composition and method disclosed by Duclos et al. with respect both to the relative configuration of the ingredients in the microparticles and with respect to the presence of water in the current composition and method which is not disclosed by Duclos et al.

Ecanow (US 4,963,367)

The composition and method of Ecanow (US 4,963,367) are different from the composition and method of the current invention.

Ecanow discloses a composition of "an aqueous emulsion of coacervate-based matrix particles containing... a physiologically-active compound, said coacervate-based matrix comprising water,... and said physiologically-active compound solubilized therein, said particles having an encapsulating coacervate-based film surrounding the particles" (Ecanow, claim 1). The pharmaceutical composition of the current application consists essentially of water and submicron to micron size solid fenofibrate microparticles... with surfaces having a combination of phospholipid and one or more nonionic, anionic or cationic surface modifier(s) coated or adhered thereon" (see new claim 16). In Ecanow, the physiologically-active compound in the emulsion particle is dissolved in the coacervate-based matrix (see Ecanow, claim 1). However, in the present

application, the fenofibrate is not dissolved but is a solid in the solid fenofibrate microparticle (see current application, new claim 16).

In Ecanow, water is a component of the "coacervate-based matrix" in which the physiologically-active compound is dissolved (see Ecanow, claim 1). The water in the coacervate-based matrix is selected from the group consisting of coacervate phase water, equilibrium phase water, and mixtures thereof. In the current application, water is not inside of the solid fenofibrate microparticles. Rather, the solid fenofibrate microparticles have a combination of phospholipid and one or more surface modifier(s) coated or adhered on their surfaces, where the hydrophilic portion of the surface modifier(s) is sticking into water and the lipophilic portion is adsorbed at the surface of the microparticle (see current application, new claim 16).

The process disclosed in Ecanow involves "forming a mixture of one or more surface active agents, water and one or more physiologically-active compounds to produce a two phase aqueous coacervate composition containing said compound, and emulsifying the composition to produce an aqueous emulsion of coacervate-based matrix particles containing the physiologically-active compound, said coacervate-based matrix comprising water selected from the group consisting of coacervate phase water, equilibrium phase water, and mixtures thereof, and said physiologically-active compound solubilized therein, said particles having an encapsulating coacervate-based film surrounding the particles" (see Ecanow, claim 1) However, microemulsions are well known to comprise liquid materials rather than solid materials such as solid fenofibrate particles to which energy is applied in the method of the current invention and such as

solid fenofibrate microparticles produced in the method of the current invention (see current application, new claim 16).

Applicants await examination of claims 16-32.

Respectfully submitted,

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